



PAN AMERICAN HEALTH ORGANIZATION  
WORLD HEALTH ORGANIZATION



## **38th SESSION OF THE SUBCOMMITTEE ON PLANNING AND PROGRAMMING OF THE EXECUTIVE COMMITTEE**

*Washington, D.C., USA, 24-26 March 2004*

---

*Provisional Agenda Item 7*

SPP38/6 (Eng.)  
5 February 2004  
ORIGINAL: ENGLISH

### **ACCESS TO MEDICINES**

#### **Promoting Access to Strategic Public Health Supplies**

1. Expanding access to essential medicines and other critical public health commodities is a global priority and must be viewed within the context and recognition of the importance of the right to health for all.\* The attainment of the global mandates presented through the United Nations Millennium Declaration, September 2000, and the identification of two priority public health targets (on the one hand HIV/AIDS, malaria, and other major diseases, and on the other the reduction of child mortality), will require access to essential public health supplies. In addition, Target No. 17 of the Millennium Development Goals explicitly highlights the need to “provide access to affordable essential medicines in developing countries.”

2. Between 1997 and 2003, it is estimated that the number of persons having access to essential medicines increased globally from 2.1 billion to 4 billion. Despite this significant improvement, approximately 2 billion, or one-third of the world’s population still does not have access to affordable quality medicines: only 27% of TB patients have access to Directly Observed Therapy, Short-course (DOTS) even though a six-month drug treatment can cost as little as US\$ 10, and less than 53% of persons living with HIV/AIDS in the Region of the Americas have access to antiretroviral therapy (ART), despite significant reductions in the prices of antiretrovirals during the last three years.

3. The number and variety of other medicinal products, and especially blood products, diagnostics, and vaccines being produced at the global level continues to increase. But in many developing countries within the Region, essential medicines and other public health supplies are not readily available, or if available not affordable to the

---

\* WHO Statement to the UN Commission on Human Rights, Agenda Item 10, Economic, Social, and Cultural Rights, Geneva, April 1, 2003.

poorest segments of the population. Inadequate financing and financing systems result in inequitable access, and poorly developed supply systems hinder continuity in product availability. In addition, inadequate capacity in product assessment and regulation and irrational commodity use often means that access to quality products cannot be ensured.

4. Tackling the complex issue of access to public health supplies, with focus on priority diseases, is becoming ever more urgent in the Region of the Americas, and requires a new and intensified effort. The approach must address the principal determinants of access; build on existing strategies, initiatives, and mechanisms; and involve the participation of all stakeholders in the provision and use of essential public health supplies. ‘

### **Challenges for PAHO in Access to Public Health Supplies**

5. The challenges facing Member States in improving access to essential public health supplies lie principally in important areas of selection of quality products, financing and procurement, cost containment, and supply management. The selection of essential public health supplies is often not based on rational criteria resulting in the availability and use of inappropriate commodities. Sources of commodities are often selected based on price alone, and without appropriate consideration of product quality and quality assessment of manufacturers and suppliers.

6. Price information is often not readily available to facilitate referencing in procurement, and there is insufficient information on pricing policies and methodologies being applied. Too often essential drugs are inaccessible to the poor because of high price: differential pricing policies are not necessarily equity-based.

7. Due consideration has not been afforded to the importance of supply management systems, programming, and planning in ensuring the continued availability of public health supplies.

8. There is insufficient information available to countries in effective cost containment methods, including provisions and safeguard options in national intellectual property regulation to protect and promote access to essential public health supplies. More information is required concerning the impact of trade agreements in the Region on access to essential public health supplies.

9. Mechanisms and options for the financing of essential public health supplies in the Region vary considerably but little has been documented concerning options and best practices by resource setting. It is recognized, however, that essential public health commodities can consume as much as 25% of household expenditure in some countries in the Region.

10. Although multisource drugs are used widely in the Region, regulatory definitions vary widely between countries hindering the rapid registration among Member States. Few countries in the Region have effectively implemented generic policies with strong regulatory requirements in combination with incentives for the development of the generic markets, acceptance, and rational generic drug use, hindering access to the most cost-effective public health commodities required for the provision of primary care.

11. Although pooled procurement of vaccines has been effective in the Region, other initiatives for pooled procurement have had limited success to date due to factors such as political and financial commitment, harmonization of quality criteria and inadequate joint programming and planning.

### **Elements of the PAHO Response in Promoting Access to Public Health Supplies**

12. The Essential Medicines, Vaccines, and Health Technology Unit, within the Area of Technology and Health Services Delivery (THS/EV), under the Office of the Assistant Director, promotes, coordinates, and implements technical cooperation activities aimed at strengthening national and regional capacity to improve accessibility, rational use, and regulation of essential medicines, and quality laboratory/blood services. Country offices provide direct technical cooperation in this area, specific to the needs of the country and with the support of THS/EV. Within its scope of work, THS/EV coordinates technical cooperation in access to essential public health supplies used in the delivery of health services. Interarea and interinstitutional cooperation are promoted to ensure that core areas of work are coherent with the overarching objectives of the priority regional programs such as HIV/AIDS, TB, and malaria; other priority emerging noncommunicable diseases; and the development of primary health care in the Region.

13. PAHO has contributed to improving access to quality medicines in Member States through the regional program of work in medicines. Countries receive support in developing pharmaceutical policies that promote principles of equitable access, and use tools to measure the policy performance. PAHO acts as the Secretariat of the Pan American Network for Drug Regulatory Harmonization (PANDHR), a highly participative and operational association of drug regulatory authorities and other stakeholders in the Region working to harmonize standards in key areas such as Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), bioequivalence, and quality control of pharmaceuticals amongst others. Through joint programs with other partners, the rational use of drugs is promoted including greater access to scientific and patient information. The program of work in medicines is guided by the WHO Medicines Strategy, adapted to the needs and specificities of PAHO Member States.

14. In 2000, PAHO established at the request of Member States the Regional Revolving Fund for Strategic Public Health Supplies (Strategic Fund) to support

countries in the source selection and access to priority medicines used in HIV, TB, malaria, and leishmaniasis. The Fund aims to facilitate the procurement of low-cost priority essential public health supplies and at the same time build capacity in drug supply management and procurement programming and planning. One-third of PAHO Member States have signed agreements for participation in the Strategic Fund, and even if the use of the Fund as a procurement mechanism has been limited to a few countries to date, the potential of the fund as a regional supply mechanism for priority public health commodities is recognized within the context of PAHO support to Global Fund recipient countries as well as countries participating in key global initiatives such as 3 by 5.

15. Within the framework of the PAHO/WHO Expanded Program for Immunization, PAHO provides support to Member States in the selection, procurement, supply, and use of vaccines through the PAHO Revolving Fund for Vaccine Procurement (EPI Revolving Fund), managed by the Unit of Immunizations (FCH/IM). Further support is provided to Member States to strengthen capacity in the quality assessment of vaccines in use throughout the Region.

16. As the Region moves towards the 100% screening of blood transfusions for HIV, HCV, HVB, and other transfused infections, technical cooperation is provided to countries in the selection, supply, and use of diagnostics and other medicinal products derived from blood directly through the regional program and/or through collaborating and specialized subregional centers. The availability and use of diagnostics is improved through the work program in developing clinical and public health laboratory networks and the development of diagnostic procedures for priority diseases.

### **Proposed Principal Lines of Action for a PAHO Work Program in Essential Public Health Supplies, Access, and the Strategic Fund**

17. Based on the core competencies of PAHO, focusing on the countries as primary recipients and partners in technical cooperation and recognizing the multiplicity and capacity of actors and stakeholders in the field, a focused approach is proposed to improve access, and in particular, the availability and affordability of quality public health supplies in the Region. The approach aims to focus on determinants of access and aims to address key issues in the selection and supply of public health commodities in priority diseases, building on the comparative advantage that PAHO has in key areas, and identifying networks and partners to share experience and build capacity in other areas. The strategy will complement work currently being executed by PANDHR and will be integrated with the program of work in key initiatives such as the 3 by 5 among others to promote access to priority products in HIV/AIDS, malaria and TB.

18. Four principal strategic lines of action are proposed:
- Promoting coherent generic drug policy as a means to increase the availability and use of quality essential medicines. The strategy proposes to build on the principal advantage presented by generics, namely as cost-effective medicines in the delivery of health care, through the exchange of experience in generic policy in the region, the development of the regulatory framework and approaches to promote increased availability and the rational use of generic drugs. The assessment and promotion of incentives to increase availability and affordability of generics, as well as those aimed at the prescriber and user to improve acceptance, will provide countries in the region with options in the development and implementation of policy.
  - Developing cost containment strategies for Essential Public Health Supplies, with focus on two areas: pricing and intellectual property. In the area of pricing, the strategy proposes the development and implementation of approaches for measurement, assessing the impact and use of information, the role of competition, pricing methodologies and options for price control. In the area of intellectual property, the impact on access to medicines will continue to be assessed. Information exchange will be promoted to assess if pharmaceutical policies and regulations promote access to medicines through the implementation of provisions and options provided for within international agreements.
  - Strengthening public health commodity supply systems to ensure continuity and availability. A review of drug supply management core components, from selection through procurement, stock management to distribution and use, will permit the assessment of practices and the identification of options by resource setting and health system structure. Country support in elements of supply management will strengthen capacity at the national level to ensure continuity in product availability.
  - Developing regional pooled procurement mechanisms, such as the PAHO Strategic Fund, as a viable option in the supply of low-cost quality essential public health supplies. The development of the fund will strengthen capacity in procurement, programming and planning at the country level, lead to economies of scale through the consolidation of requirements, and promote continuity in supply through the development of the cyclical procurement system. The operational framework for the Fund will be reviewed including the development of a country advisory mechanism for the Fund, and a strategy for the generation of Fund capital developed.

**Action by the Subcommittee on Planning and Programming**

19. The Subcommittee is requested to provide guidance in this field on the four proposed strategic lines of action for PAHO's work.

- - -